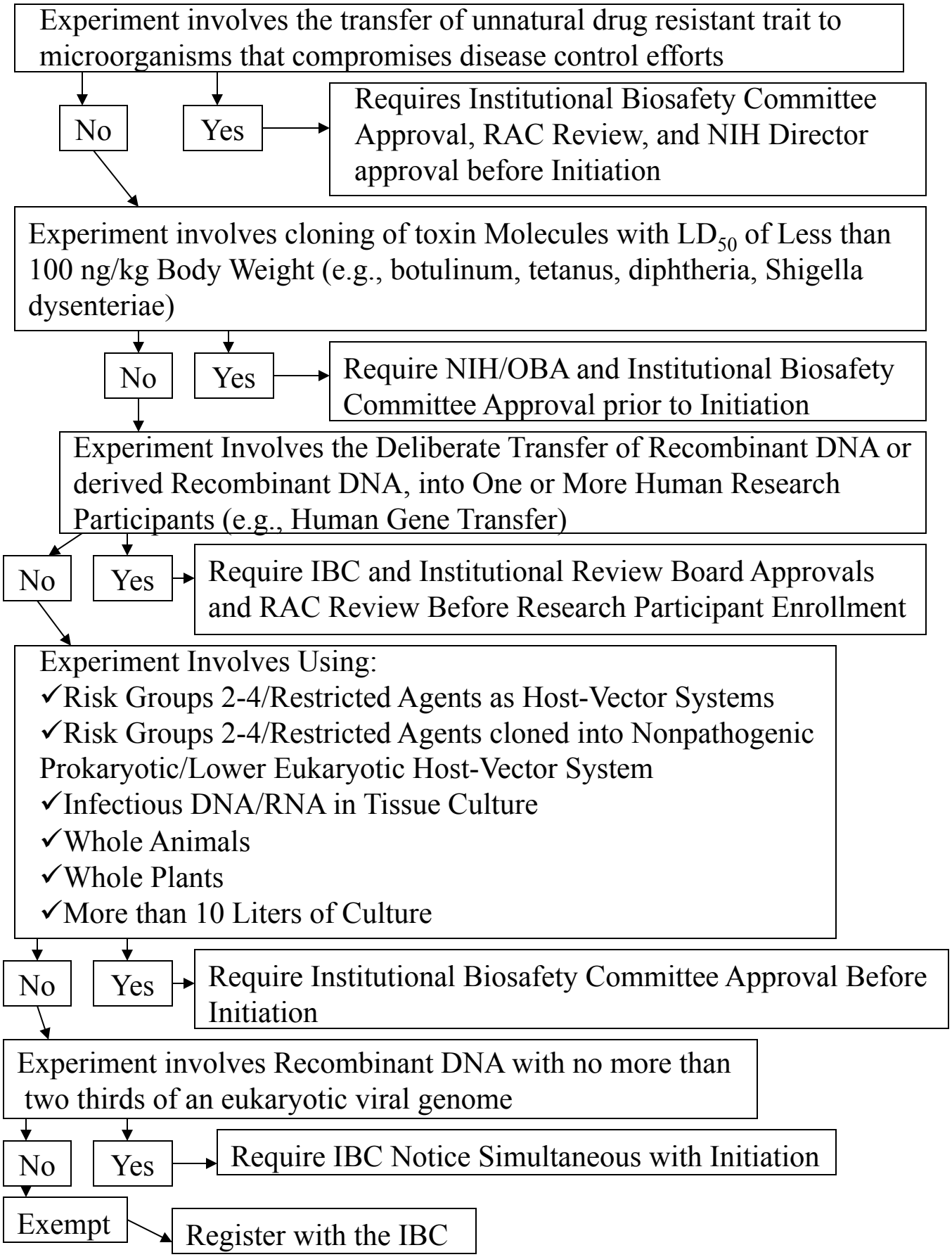
Experiment involves the transfer of unnatural drug resistant trait to microorganisms that compromises disease control efforts
No
Yes
Requires Institutional Biosafety Committee Approval, RAC Review, and NIH Director approval before Initiation
Experiment involves cloning of toxin Molecules with LD_{50} of Less than 100 ng/kg Body Weight (e.g., botulinum, tetanus, diphtheria, Shigella dysenteriae)
No
Yes
Require NIH/OBA and Institutional Biosafety Committee Approval prior to Initiation
Experiment Involves the Deliberate Transfer of Recombinant DNA or derived Recombinant DNA, into One or More Human Research Participants (e.g., Human Gene Transfer)
No
Yes
Require IBC and Institutional Review Board Approvals and RAC Review Before Research Participant Enrollment
Experiment Involves Using:
✓Risk Groups 2-4/Restricted Agents as Host-Vector Systems
✓Risk Groups 2-4/Restricted Agents cloned into Nonpathogenic Prokaryotic/Lower Eukaryotic Host-Vector System
✓Infectious DNA/RNA in Tissue Culture
✓Whole Animals
✓Whole Plants
✓More than 10 Liters of Culture
No
Yes
Require Institutional Biosafety Committee Approval Before Initiation
Experiment involves Recombinant DNA with no more than two thirds of an eukaryotic viral genome
No
Yes
Require IBC Notice Simultaneous with Initiation
Exempt
Register with the IBC

Risk Assessment Factors

When evaluating your experiment's risk, the level of risk involves your agent and the process of manipulation in terms of the following conditions?

- Virulence
- Pathogenticity
- Infectious Dose
- Environmental Stability
- Route of Spread
- Communicability
- Operations
- Quantity
- Availability of Vaccine or Treatment
- Gene Product Effects
  - Toxicity
  - Physiological Activity
  - Allergenicity

For the Risk Group Level of your agent, consult Appendix B "Classification of Human Etiological Agents on the Basis of Hazard" of the *NIH Guidelines*